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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,371	08/27/2001	Gust H. Bardy	032580.0004.CIP1	5209
22440	7590	05/21/2004	EXAMINER	
GOTTLIEB RACKMAN & REISMAN PC			DROESCH, KRISTEN L	
270 MADISON AVENUE			ART UNIT	PAPER NUMBER
8TH FLOOR			3762	
NEW YORK, NY 100160601				

DATE MAILED: 05/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/940,371	BARDY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kristen L Drosch	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 30 March 2004.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) See Continuation Sheet is/are pending in the application.  
 4a) Of the above claim(s) 3,20,21,32,44,48,59,60,98,99,122 and 150 is/are withdrawn from consideration.  
 5) Claim(s) 1,2,5-8,10-19,22-27,46-48,50-53,55-58 and 61-73 is/are allowed.  
 6) Claim(s) See Continuation Sheet is/are rejected.  
 7) Claim(s) 28-31,34-37,39-45,87-89,93-97,125,153 and 164 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 30 March 2004 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Continuation of Disposition of Claims: Claims pending in the application are 1-3,5-8,10-32,34-37,39-48,50-53,55-73,85-105,118-122,124-128,149,150 and 152-165.

Continuation of Disposition of Claims: Claims rejected are 85-86, 90-92, 100-105, 118-121, 124, 126-128, 149, 152, 154-163, and 165 .

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Species X in Paper No. 9 is acknowledged.
2. Claims 3, 20-21, 32, 44, 48, 59-60, 98-99, 122, and 150 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable *generic* or linking claim. Election was made **without** traverse in Paper No. 9.

### ***Claim Objections***

3. Claims 28, 118, and 164 are objected to because of the following informalities: "a cardioversion defibrillation circuitry". The examiner suggests either "a cardioversion defibrillation circuit" or "cardioversion defibrillation circuitry". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. 85-86, 90, 100, 103-105, 118-121, 124, 126-128, 149, 152, 154-158, 160-163, and 165 are rejected under 35 U.S.C. 102(b) as being anticipated by Hauser et al. (5,385,574).

The functional language and introductory statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art.

With respect to claim 85, 118, 149, and 165, Hauser et al. shows an ICD comprising a housing comprising a mixture of conductive and non-conductive materials wherein at least a

Art Unit: 3762

portion of the housing is curved (the edges); an electrical circuit (18) and at least one electrically conductive surface (electrode) integrally positioned on a portion of the housing (14, 14', 52, 62, 64, 66, 80) and coupled to the electrical circuit (Figs. 1, 3, 8, and 11; Col. 6, lines 49-60).

With respect to claims 86, 124, and 152, Hauser et al. shows the housing comprises a mixture of ceramic and titanium (Col. 6, lines 49-60).

Regarding claim 90, Hauser et al. shows the curved portion (the edges) of the housing comprises a circular arc approximately 1 radians to 180 radians in length (Fig. 11).

With respect to claims 100, and 158, Hauser et al. shows the electrical circuit can provide cardioversion defibrillation (Abs).

Regarding claims 103, 119 146, and 161, Hauser et al. shows the electrically conductive surface (electrode) (14, 14', 52, 62, 64, 66, 80) can emit energy for shocking the patient's heart (Col. 2, lines 29-34).

Regarding claims 104-105, 120-121, 147-148, and 162-163 Hauser et al. shows the electrically conductive surface can receive sensory information (Col. 7, lines 9-15).

Regarding claim 126, Hauser et al. shows the predetermined relationship is with respect to the patient's heart.

With respect to claims 128, and 160, Hauser et al. shows the circuitry provides waveform cardiac pacing for a patient's heart (Col. 5, lines 27-32).

With respect to claims 154-155, Hauser et al. shows the bottom surface and top surface of the housing are substantially smooth (Fig. 11)

With respect to claim 156, Hauser et al. shows the bottom surface (surface that faces the heart) further comprises a proximal end and a distal end, wherein an electrode (62) is integrally positioned at the proximal end (left) of the bottom surface (Fig. 11).

Regarding claim 157, Hauser et al shows a second electrode (64) is integrally positioned at the distal end (right) of the bottom surface (Fig. 11).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 91-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al. (5,385,574). Hauser et al. discloses the claimed invention except for the curved portion, non-planar bottom surface, or non-planar top surface comprising an elliptical curve or a nonsymmetrical arc. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the curved portion, non-planar bottom surface, or non-planar top surface as taught by Hauser et al. with an elliptical curve or nonsymmetric arc, since applicant has not disclosed that these particular types of curves provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any curve such as the curve taught by Hauser et al. for forming the edge of the curved portion, non-planar bottom surface, or non-planar top surface.

8. Claims 101-102, and 159 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al. (5,385,574) as applied to claims 1, 22, 46, 68, 83, 85, 100, 130, 144, and 159 above

Art Unit: 3762

and further in view of Mower (5,871,506). Hauser et al. discloses the claimed invention except for setting forth the specific waveforms utilized in cardiac pacing. Mower teaches using biphasic waveforms for cardiac pacing in order to improve cardiac conduction and contraction (Col. 2, lines 42-53). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to apply monophasic, biphasic pacing pulses as Mower teaches with the device of Hauser et al. since they are well known in the art and the application of biphasic pulses provides the advantage of improving cardiac conduction and contraction.

***Response to Arguments***

9. Applicant's arguments filed 3/30/04 with respect to claims 85-86, 90-92, 100-105, 118-121, 124, 126-128, 149, 152, 154-159, 160-163, and 165 have been fully considered but they are not persuasive. Although applicant states that the mixture includes both conductive and nonconductive materials within the mixture composition, this limitation does not appear in the claims. The examiner is to apply the broadest reasonable interpretation to pending claims pursuant to MPEP § 2111. Microsoft Bookshelf Basics dictionary defines a mixture as "One that consists of diverse elements". Furthermore, in paragraph 175 of applicant's specification; applicant states that the housing segments 510 and 512 can comprise a mixture of ceramic and titanium materials. In the next few sentences, applicant explains that housing segments 510 and 512 are made of titanium, the insulating plates 518 and 524 are made of ceramic material, and the conductive plates 520 and 522 are made of titanium or other suitable metals. In conclusion, the examiner asserts that the interpretation of "mixture" is reasonable, and the claims read on the Hauser reference.

***Allowable Subject Matter***

10. Claims 87-89, 93-97, 125, and 153 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Claims 1-2, 5-8, 10-19, 22-27, 46-48, 50-53, 55-58, 61-73 are allowed.

12. Claims 28-31, 34-37, 39-45, and 164 would be allowable if rewritten to overcome the objection(s) for minor informalities set forth in this Office action.

***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Dahlberg (5,769,874) shows a defibrillator housing comprising "cermet". Leysieffer (6,269,266) describes implantable medical device housings comprising metal ceramic composite.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 3762

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Drosch whose telephone number is 703-605-1185.

The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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